RULES
OF
THE TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-8-15
STANDARDS FOR RESIDENTIAL HOSPICES

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1200-8-15-.01 DEFINITIONS.

(1) Administrator. An individual appointed by a governing body who is responsible for the day to day management of the hospice program.

(2) Advance Directive. A written statement such as a living will, a durable power of attorney for health care or a do not resuscitate order relating to the provision of health care when the individual is incapacitated.

(3) Bereavement Counseling. Counseling services provided to the patient's or resident's family both prior to and after the patient's or resident's death.

(4) Bereavement Counselor. An individual who has at least a bachelor's degree in social work, counseling, psychology, pastoral care, or specialized training or experience in bereavement theory and counseling.

(5) Board. The Tennessee Board for Licensing Health Care Facilities.

(6) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient or resident, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilations or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient or resident where cardiac or respiratory arrest has occurred or is believed to be imminent.

(7) Certified Master Social Worker. A person currently certified as such by the Tennessee Board of Social Worker Certification and Licensure.

(8) Clinical Note. A written and dated notation containing a patient or resident assessment, responses to medications, treatments and services, and/or any changes in condition signed by a health team member who made contact with the patient or resident.

(9) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(10) Competent. For purposes of this chapter, a patient or resident who has decision-making capability.

(Rule 1200-8-15-.01, continued)

(11) Core Services. Services consisting of nursing, medical social services, physician services and counseling services.

(12) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:

(a) the action(s) implemented to prevent the reoccurrence of the unusual event,

(b) the time frames for the action(s) to be implemented,

(c) the person(s) designated to implement and monitor the action(s), and

(d) the strategies for the measurements of effectiveness to be established.

(13) Decision-making capacity. Decision-making capacity is shown by the fact that the person is able to understand the proposed procedure, its risks and benefits, and the available alternative procedures.

(14) Department. The Tennessee Department of Health.

(15) Dietitian. A person currently licensed as such by the Tennessee Board of Dietitian/Nutritionist Examiners. Persons exempt from licensure shall be registered with the American Diabetics Association pursuant to T.C.A. §63-25-204.

(16) Do Not Resuscitate (DNR) Order. An order entered by the patient's or resident's treating physician in the patient's medical records which states that in the event the patient or resident suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.

(17) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state, or federal regulations.

(18) Health care decision. A decision made by an individual or the individual's health care decision-maker, regarding the individual's health care including but not limited to:

(a) the selection and discharge of health-care providers and institutions;

(b) approval or disapproval of diagnostic tests, surgical procedures, programs of administration of medication, and orders not to resuscitate;

(c) directions to provide, withhold or withdraw artificial nutrition and hydration and all other forms of health care; and

(d) transfer to other health care facilities.

(19) Health Care Decision-maker. In the case of an incompetent patient or resident, or a patient or resident who lacks decision-making capacity, the patient's or resident's health care decision-maker is one of the following: the patient's or resident's health care agent as specified in an advance directive, the patient's or resident's court-appointed legal guardian or conservator with health care decision-making authority, or the patient's or resident's surrogate as determined pursuant to Rule 1200-8-15-.13 or T.C.A. §33-3-220.

(20) HIV Resident. An individual who is in need of domiciliary care and who has been diagnosed and certified in writing by a licensed physician as being HIV (human immunodeficiency virus) positive.

(Rule 1200-8-15-.01, continued)

(21) Home Care Organization. As defined by T.C.A. § 68-11-201 "home care organization" provides home health services, home medical equipment services or hospice services to patients on an outpatient basis in either their regular or temporary place of residence.

(22) Home Health Aide/Hospice Aide. A person who has completed a total of seventy-five (75) hours of training which included sixteen (16) hours of clinical training prior to or during the first three (3) months of employment and who is qualified to provide basic services, including simple procedures as an extension of therapy services, personal care regarding nutritional needs, ambulation and exercise.

(23) Hospice Care Clinical Coordinator. A person identified as being responsible for the clinical management of all aspects of a hospice program. The hospice clinical coordinator must have at least one (1) year of supervisory experience in hospice or home health care and be either a licensed physician or a registered nurse.

(24) Hospice Patient. An individual who:

(a) Has been diagnosed as terminally ill;

(b) Has been certified in writing by a physician to have an anticipated life expectancy of six (6) months or less; and,

(c) Has voluntarily requested admission to, and been accepted by a licensed hospice.

(25) Hospice Services. A coordinated program of care, under the direction of an identifiable hospice administrator, which provides palliative and supportive medical and other services to hospice patients and their families. Hospice services shall be provided twenty-four (24) hours a day, seven (7) days a week.

(26) Incompetent. A patient or resident who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(27) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(28) Involuntary Transfer. The movement of a patient or resident without the consent of the resident, the resident's legal guardian, next of kin or representative, with required notification to the appropriate agencies.

(29) Lacks Decision-Making Capacity. Lacks Decision-Making Capacity means the factual demonstration by the attending physician and the medical director, or the attending physician and another physician that an individual is unable to understand:

(a) A proposed health care procedure(s), treatment(s), intervention(s), or interaction(s);

(b) The risks and benefits of such procedure(s), treatment(s), intervention(s) or interaction(s); and

(c) The risks and benefits of any available alternative(s) to the proposed procedure(s), treatment(s), intervention(s) or interaction(s).

(30) Legal Guardian. Any person authorized to act for the patient or resident pursuant to any provision of T.C.A. §§34-5-102(4) or 34-11-101, or any successor statute thereto.

(31) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.

(Rule 1200-8-15-.01, continued)

(32) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(33) Licensed Psychologist. A person currently licensed as such by the Tennessee Board of Examiners in Psychology.

(34) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(35) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(36) Medical Director. A licensed physician employed by the residential hospice to be responsible for medical care in the facility.

(37) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's or resident's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(38) Medical Record. Medical histories, records, reports, clinical notes, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, and other written electronics, or graphic data prepared, kept, made or maintained in an agency that pertains to confinement or services rendered to patients and residents.

(39) Medically Futile Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or resident or to achieve the expressed goals of the informed patient or resident. In the case of the incompetent patient or resident, the surrogate expresses the goals of the patient or resident.

(40) Medical Social Services. When provided, shall be given by a certified master social worker, a licensed clinical social worker, or by a social worker or social work assistant employed by the residential hospice and under the supervision of a certified master social worker or licensed clinical social worker, and in accordance with the plan of care. The medical social services provider shall assist the physician and other team members in understanding the significant social and emotional factors related to the health problems, participate in the development of the plan of care, prepare clinical and progress notes, work with the family, utilize appropriate community resources, participate in discharge planning and in-service programs, and act as a consultant to other organization personnel.

(41) N.F.P.A. The National Fire Protection Association.

(42) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(43) Occupational Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(44) Palliative. The reduction or abatement of pain or troubling symptoms by appropriate coordination of all elements of the hospice care team to achieve needed relief of distress.

(45) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical

care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(46) Pharmacist. A person currently licensed as such by the Tennessee Board of Pharmacy.

(47) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(48) Physical Therapist Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(49) Physician. A person currently licensed as such by the Tennessee Board of Medical Examiners or currently licensed to practice osteopathy by the Tennessee Board of Osteopathic Examination.

(50) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(51) Residential Hospice. A licensed homelike residential facility designed, staffed and organized to provide hospice and/or HIV care services, except such services shall be provided at such residential facility rather than the patient's or resident's regular or temporary place of residence. A residential hospice shall not provide hospice and/or HIV care services to any person other than a hospice and/or HIV resident.

(52) Respiratory Therapist. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(53) Respiratory Therapy Technician. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(54) Respite Care. A short-term period of inpatient care provided to a hospice patient only when necessary to relieve the family members or other persons caring for the patient.

(55) Secured Unit. A facility or distinct part of a facility where the residents are intentionally denied egress by any means.

(56) Shall or Must. Compliance is mandatory.

(57) Social Worker. An individual who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education and has one (1) year of social work experience in a health care setting.

(58) Social Work Assistant. A person who has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has at least one (1) year of social work experience in a health care setting. Social work related fields include bachelor/masters degrees in psychology, sociology, human services (behavioral sciences, not human resources), masters degree in counseling fields (psychological guidance and guidance counseling) and degrees in gerontology.

(59) Speech Language Pathologist. A person currently licensed as such by The Tennessee Board of Communication Disorders and Sciences.

(60) Spiritual Counselor. A person who has met the requirements of a religious organization to serve the constituency of that organization.

(61) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board or equivalent body.

(Rule 1200-8-15-.01, continued)

(62) Supervision. Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Periodic supervision must be provided if the person is not a licensed or certified assistant, unless otherwise provided in accordance with these regulations.

(63) Surrogate. The patient's or resident's legal guardian, or if none, a competent adult most likely to know the wishes of the patient or resident with respect to the possible withholding of resuscitative services or withdrawal of resuscitative services.

(64) Terminally ill. An individual with a medical prognosis that his or her life expectancy is six (6) months or less if the illness runs its normal course.

(65) Transfer. The movement of a patient or resident at the direction of a physician or other qualified medical personnel when a physician is not readily available, but does not include such movement of a patient or resident who leaves the facility against medical advice.

(66) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.

(67) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.

(68) Volunteer. An individual who agrees to provide services to a hospice care patient or HIV resident and/or family member(s), without monetary compensation, with appropriate supervision by the facility.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, and 68-11-224.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003.*

1200-8-15-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or any state, county or local government unit, or any division, department, board or agency thereof shall establish, conduct, operate, or maintain in the State of Tennessee any residential hospice without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure and for the geographic area specified by the certificate of need or at the time of the original licensing. The name of the residential hospice shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the residential hospice.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the department.

(b) Each applicant for a license shall pay an annual license fee based on the number of beds as follows:

1.	Less than 25 beds	$	600.00
2.	25 to 49 beds, inclusive	$	800.00
3.	50 to 74 beds, inclusive	$	950.00

4. 75 to 99 beds, inclusive $ 1,100.00

5. 100 to 124 beds, inclusive $ 1,250.00

6. 125 to 149 beds, inclusive $ 1,400.00

7. 150 to 174 beds, inclusive $ 1,550.00

8. 175 to 199 beds, inclusive $ 1,700.00

For residential hospice of two hundred (200) beds or more the fee shall be one thousand seven hundred dollars ($1,700.00) plus one hundred fifty dollars ($150.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients or residents shall not be admitted to the residential hospice until a license has been issued. Applicants shall not hold themselves out to the public as being a residential hospice until the license has been issued. A license shall not be issued until the residential hospice is in substantial compliance with these rules and regulations, including submission of all information required by T.C.A. § 68 -11-206(l) or as later amended, and all information required by the commissioner.

(d) The applicant must prove the ability to meet the financial needs of the residential hospice.

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.

(a) For the purposes of licensing, the licensee of a residential hospice has the ultimate responsibility for the operation of the residential hospice, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the residential hospice’s operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the residential hospice is owned and operated.

(c) Transactions constituting a change of ownership include, but are not limited to the following:

1. Transfer of the residential hospice’s legal title;

2. Lease of the residential hospice’s operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the residential hospice;

4. One partnership is replaced by another through the removal, addition or substitution of a partner;

(Rule 1200-8-15-.02, continued)

5. Removal of the general partner or general partners, if the residential hospice is owned by a limited partnership;

6. Merger of a residential hospice owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

7. The consolidation of a corporate residential hospice owner with one or more corporations; or,

8. Transfers between levels of government.

(d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:

1. Changes in the membership of a corporate board of directors or board of trustees;

2. Two (2) or more corporations merge and the originally-licensed corporation survives;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or,

5. Corporate stock transfers or sales, even when a controlling interest.

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the residential hospice. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the residential hospice's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the exact same legal form as the former owner.

(4) To be eligible for a license or renewal of a license, each residential hospice shall be periodically inspected for compliance with these regulations. If deficiencies are identified, an acceptable plan of correction shall be established and submitted to the department.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed November 19, 2003; effective February 2, 2004.*

1200-8-15-.03 DISCIPLINARY PROCEDURES.

(1) The board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

(b) Violation of the rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act in the residential hospice;

(d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients or residents of the residential hospice; or

(e) Failure to renew the license.

(Rule 1200-8-15-.03, continued)

(2) The board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the residential hospice;

(c) The conduct of the residential hospice in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and,

(d) Any prior violations by the residential hospice of statutes, regulations or orders of the board.

(3) When a facility is found by the department to have committed a violation of this chapter, the department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies the facility must return a plan of correction indicating the following:

(a) How the deficiency will be corrected;

(b) The date upon which each deficiency will be corrected;

(c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and

(d) How the corrective action will be monitored to ensure that the deficient practice does not recur.

(4) Either the failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject the facility's license to possible disciplinary action.

(5) Any licensee or applicant for a license aggrieved by a decision or action of the department or board pursuant to this chapter may request a hearing before the board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Administrative Procedures Act, T.C.A. §§ 4-5-101, et seq.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, and 68-11-206 through 68-11-209.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000.*

1200-8-15-.04 ADMINISTRATION.

(1) The residential hospice shall have a full-time (working at least 32 hours per week) administrator. Any change of administrators shall be reported in writing to the department within fifteen (15) days. The administrator shall designate in writing an individual to act in his/her absence in order to provide the residential hospice with administrative direction at all times. The administrator shall assure the provision of appropriate fiscal resources and personnel required to meet the needs of the patients and/or residents.

(2) The residential hospice must organize, manage, and administer its hospice and HIV care services to attain and maintain the highest obtainable quality of life for each patient and resident in a manner consistent with acceptable standards of practice.

(3) The residential hospice shall ensure a framework for addressing issues related to care at the end of life.

(Rule 1200-8-15-.04, continued)

(4) The residential hospice shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

(5) Nursing services, physician services, drugs and biologicals shall routinely be available on a 24-hour basis.

(6) All other hospice services shall be available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of terminal illness or conditions directly attributable to the terminal diagnosis.

(7) A residential hospice may contract for another individual or entity to furnish services, other than core services, to the residential hospice's patients or HIV residents. If services are provided under agreement or contract, the residential hospice must meet the following standards:

(a) Continuity of care. The residential hospice assures the continuity of resident and patient/family care.

(b) Written agreement. The residential hospice has a legally binding written agreement for the provision of contracted hospice services. The agreement must include at least the following:

1. Identification of the services to be provided.

2. A stipulation that services may be provided only with the express authorization of the residential hospice.

3. The manner in which the contracted services are coordinated, supervised, and evaluated by the residential hospice.

4. The delineation of the role(s) of the residential hospice and the contractor in the admission process, resident and patient/family assessment, and the interdisciplinary group care conferences.

5. Requirements for documenting that services are furnished in accordance with the agreement.

6. The qualifications of the personnel providing the services.

(c) Professional management responsibility. The residential hospice retains professional management responsibility for those contracted services and ensures that they are furnished in a safe and effective manner by persons meeting the qualifications of this part, and in accordance with the patient's and/or HIV resident's plan of care and the other requirements of this part.

(d) Financial responsibility. The residential hospice retains responsibility for payment for services.

(8) The facility shall make reasonable efforts to safeguard personal property and promptly investigate complaints of such loss. A record shall be prepared of all clothing, personal possessions, and money brought by the patient and/or HIV resident to the residential hospice at the time of admission. The record shall be filled out in duplicate. One copy of the record shall be given to the patient or resident or the patient's or resident's representative and the original shall be maintained in the residential hospice record. This record shall be updated as additional personal property is brought to the facility.

(9) If the facility keeps patient or resident funds, such funds shall be kept in an account separate from the facility's funds. Patient or resident funds shall not be used by the facility. The facility shall maintain and allow each patient or resident access to a written record of all financial arrangements and transactions involving the individual patient's or resident's funds. The facility shall provide each

patient and resident or his/her representative with a written itemized statement at least quarterly of all financial transactions involving the patient's or resident's funds.

(10) Within thirty (30) days of a patient's or resident's death, the facility shall provide an accounting of the patient's or resident's funds held by the facility and an inventory of the patient's or resident's personal property held by the facility to the patient's or resident's executor, administrator or other person authorized by law to receive the decedent's property. The facility shall obtain a signed receipt from any person to whom the decedent's property is transferred.

(11) Upon the sale of the facility, the seller shall provide written verification that all the patient's or resident's funds and property have been transferred and shall obtain a signed receipt from the new owner. Upon receipt, the buyer shall provide, to the patients and resident's, an accounting of funds and property held on their behalf.

(12) When licensure is applicable for a particular job, verification of the current license must be included as a part of the personnel file. Each personnel file shall contain accurate information as to the education, training, experience and personnel background of the employee. Documentation that references were verified shall be on file. Adequate medical screenings to exclude communicable disease shall be required of each employee.

(13) Whenever the rules and regulations of this chapter require that a licensee develop a written policy, plan, procedure, technique, or system concerning a subject, the licensee shall develop the required policy, maintain it and adhere to its provisions. A residential hospice which violates a required policy also violates the rule and regulation establishing the requirement.

(14) Policies and procedures shall be consistent with professionally recognized standards of practice.

(15) No residential hospice shall retaliate against or, in any manner, discriminate against any person because of a complaint made in good faith and without malice to the board, the department, the Department of Human Services Adult Protective Services, the long term care ombudsman, the Comptroller of the State Treasury, or any government agency. A residential hospice shall neither retaliate, nor discriminate, because of information lawfully provided to these authorities, because of a person's cooperation with them, or because a person is subpoenaed to testify at a hearing involving one of these authorities.

(16) Each residential hospice shall adopt safety policies for the protection of patients and residents from accident and injury.

(17) A record pertaining to the payment agreement between the residential hospice and the patient or resident shall be accomplished prior to admission. A copy of the agreement record shall be given to the patient or resident and the original shall be maintained in the facility's records.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed June 18, 2002; effective September 1, 2002.*

1200-8-15-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

(1) The residential hospice shall have a policy to admit only patients who meet the following criteria, or HIV care residents:

(a) Has been diagnosed as terminally ill;

(b) Has been certified by a physician, in writing, to have an anticipated life expectancy of six (6) months or less;

(c) Has personally, or through a representative, voluntarily requested admission to and been accepted by a licensed residential hospice; and

(d) Has personally or through a representative, in writing, given informed consent to receive hospice care.

(2) Patients shall be admitted to receive hospice services or residents admitted to receive HIV care on the basis of a reasonable expectation that the patient's or resident's medical, nursing and psychosocial needs can be met adequately by the residential hospice.

(3) Care shall follow a written plan of care established and reviewed by the attending physician, the medical director, or the physician's designee and the interdisciplinary group. Care shall continue under the supervision of the attending physician.

(4) The residential hospice staff shall determine that the patient's or resident's needs can be met by the facility's services and capabilities.

(5) Every person admitted for care or treatment to any residential hospice covered by these rules shall be under the supervision of a physician who holds a license in good standing to practice in Tennessee. The name of the patient's attending physician shall be recorded in the patient's medical record.

(6) The residential hospice staff shall obtain the patient's or resident's written consent for hospice or HIV care services.

(7) The signed consent form shall be included with the patient's or resident's individual clinical record.

(8) A diagnosis must be entered in the admission records of the residential hospice for every person admitted for care or treatment.

(9) Any admission in excess of the licensed bed capacity is prohibited except when an emergency admission is approved by the department.

(10) A medical record shall be developed and maintained for each patient or resident admitted.

(11) No patient or resident shall be discharged without a written order from the attending physician or the medical director stating the patient does not meet hospice criteria or the resident does not meet HIV care criteria, or through other legal processes, and timely notification of next of kin and/or the authorized representative.

(12) When a patient or resident is discharged, a summary of the significant findings and events of the patient's or resident's care, the patient's or resident's condition on discharge and the recommendation and arrangement for future care, if any, is required.

(13) When a patient or resident is transferred, a summary of treatment given at the residential hospice, condition of the patient or resident at time of transfer and date and place to which he is transferred shall be entered in the record. If the transfer is due to an emergency, this information will be recorded within forty-eight (48) hours, otherwise, it will precede the transfer of the patient or resident.

(14) When a patient or resident is transferred, a copy of the clinical summary shall, with consent of the patient or resident, be sent to the facility that will continue the care of the patient or resident.

(15) Except when the Board has revoked or suspended the license, a residential hospice which intends to close, cease doing business, or reduce its licensed bed capacity by ten percent (10%) or more, shall notify the Department at the earliest moment of the decision, but not later than thirty (30) days before

the action is to be implemented. The facility shall establish a protocol, subject to the Department's approval, for the transfer or discharge of the patients and/or residents. Should the residential hospice violate the provisions of this subsection, the department shall request the Attorney General of the State of Tennessee to intervene to protect the patients and/or residents, as is provided by T.C.A. § 68-11-213(a).

(16) The residential hospice shall ensure that no person on the grounds of race, color, national origin, or handicap, will be excluded from participation in, be denied benefits of, or otherwise subjected to discrimination in the provision of any care or service of the residential hospice. The residential hospice shall protect the civil rights of patients and residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

(17) Facilities utilizing secured units must be able to provide survey staff with twelve (12) months of the following performance information specific to the secured unit and its residents:

(a) Documentation that each secured patient or resident has been evaluated by an interdisciplinary team consisting of at least a physician, a social worker, a registered nurse, and a family member and/or significant other (or patient care advocate) prior to admittance to the unit;

(b) Ongoing and up-to-date documentation of quarterly review by each patient or resident's interdisciplinary team as to the appropriateness of placement in the secured unit;

(c) A current listing of the number of deaths and hospitalizations with diagnoses that have occurred on the unit;

(d) A current listing of all unusual incidents and/or complications on the unit;

(e) An up-to-date staffing pattern and staff ratios for the unit that is recorded on a daily basis. The staffing pattern must ensure that there is a minimum of one (1) attendant, awake, on duty, and physically located on the unit twenty-four (24) hours per day, seven (7) days per week at all times;

(f) A formulated calendar of daily group activities scheduled including a resident attendance record for the previous three (3) months;

(g) An up-to-date listing of any incidences of decubitus and/or nosocomial infections, including resident identifiers; and,

(h) Documentation showing that 100% of the staff working on the unit receives and has received annual in-service training which shall include, but not be limited to the following subject areas:

1. Basic facts about the causes, progression and management of Alzheimer's Disease and related disorders;

2. Dealing with dysfunctional behavior and catastrophic reactions in the residents;

3. Identifying and alleviating safety risks to the resident;

4. Providing assistance in the activities of daily living for the resident; and,

5. Communicating with families and other persons interested in the resident.

(Rule 1200-8-15-.05, continued)

***Authority**: T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209. **Administrative History:** Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000.*

1200-8-15-.06 BASIC HOSPICE FUNCTIONS.

(1) Core Functions. A residential hospice must ensure that substantially all core services are routinely provided directly by hospice employees. A residential hospice may use contracted staff if necessary to supplement residential hospice employees in order to meet the needs of patients and residents.

(a) Nursing services. The residential hospice must provide nursing care and services by, or under the supervision of, a registered nurse (R.N.) at all times.

1. Nursing services must be directed and staffed to assure the nursing needs of patients and residents are met.

2. Patient and resident care responsibilities of nursing personnel must be specified.

3. Hospice services and HIV care services must be provided in accordance with recognized standards of practice.

4. Nursing services include the authorization of a Registered Nurse to pronounce the death of a patient or resident.

(b) Medical Social Services. Medical Social Services must be provided by a qualified social worker under the direction of a physician.

(c) Physician Services. In addition to palliation and management of terminal illness and related conditions and HIV care, physician employees of the residential hospice including the physician member(s) of the interdisciplinary group, must also meet the general medical needs of the patients and residents to the extent these needs are not met by the attending physician.

(d) Counseling Services. Counseling services must be made available to both the individual and the family. Counseling includes bereavement counseling, provided both prior to and after the patient's or resident's death, as well as dietary, therapeutic, spiritual and may include any other counseling services identified in the plan of care for the individual and family provided while the individual is a patient or resident of the residential hospice.

1. Bereavement counseling. There must be an organized program for the provision of bereavement services under the supervision of a qualified professional. The plan of care for these services should reflect family needs, services to be provided, and the frequency of services.

2. Dietary counseling. Dietary counseling, when required, must be provided by a qualified individual.

3. Spiritual counseling. Spiritual counseling must include notice to patients as to the availability of clergy.

4. Additional counseling. Counseling may be provided by other members of the interdisciplinary group as well as by other qualified professionals as determined by the residential hospice.

(2) Plan of Care.

A written plan of care must be established and maintained for each individual admitted to a residential hospice, and the care provided to an individual must be in accordance with the plan.

(a) Establishment of plan. The plan must be established by the attending physician, the medical director or the physician's designee and the interdisciplinary group prior to providing care.

(b) Review of plan. The plan must be reviewed and updated as the patient's condition changes, but at intervals of no more than (14) days, by the attending physician, the medical director or the physician designee and the interdisciplinary group. These reviews must be documented.

(c) Content of plan. The plan must include an assessment of the individual's needs and identification of the HIV care services or hospice services required including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's or resident's and family's needs.

(3) Interdisciplinary Group.

The organization providing hospice services must designate an interdisciplinary group and groups composed of individuals who provide or supervise the care and services offered by the residential hospice:

(a) Composition of Group. The residential hospice must have an interdisciplinary group or groups that include at least the following individuals who are employees of the residential hospice:

1. A doctor of medicine or osteopathy;

2. A registered nurse;

3. A social worker; and

4. A pastoral or other counselor.

(b) Role of Group. The interdisciplinary group is responsible for:

1. Participation in the establishment of the plan of care;

2. Provision or supervision of the quality of hospice care and services and/or HIV care services;

3. Periodic review and updating of the plan of care for each individual receiving hospice care or HIV care; and

4. Establishing and maintaining policies governing the day-to-day provision of hospice care and services and/or HIV care and services.

(c) If a residential hospice has more than one interdisciplinary group, it must designate in advance the group it chooses to execute the functions described in paragraph (b)(4) of this section.

(d) Coordinator. The residential hospice must designate a registered nurse to coordinate the implementation of the plan of care of each patient and/or resident.

(e) Volunteers. The residential hospice may use volunteers, in defined roles, under the supervision of a designated residential hospice employee.

(Rule 1200-8-15-.06, continued)

1. Training. The residential hospice must provide appropriate orientation and training that is consistent with acceptable standards of residential hospice practice.

2. Role. Volunteers may be used in administrative or direct patient or resident care roles.

3. Recruiting and retaining. The hospice must document active and ongoing efforts to recruit and train volunteers.

4. Availability of clergy. The residential hospice must make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to patients or residents who request such visits and must advise patients and/or residents of this opportunity.

(4) Continuation of Care. A residential hospice must assist in coordinating continued care should the patient or resident be transferred or discharged from the residential hospice.

(5) Drug and Treatments. Drugs and treatments shall be administered by appropriately licensed facility personnel acting within the scope of their license. Oral orders for drugs and treatments shall be given to appropriately licensed personnel acting within the scope of their licenses, immediately recorded, signed and dated, and countersigned and dated by the physician.

(6) Performance Improvement Program. The residential hospice must ensure that there is an effective facility-wide performance improvement program to evaluate resident care and performance of the organization. The performance improvement program must be ongoing and have a written plan of implementation which assures that:

(a) All organized services related to resident care, including services furnished by a contractor, are evaluated;

(b) Nosocomial infections and medication therapy are evaluated;

(c) All services performed in the facility are evaluated as to the appropriateness of diagnosis and treatment;

(d) The residential hospice must have an ongoing plan, consistent with available community and facility resources, to provide or make available services that meet the medically-related needs of its patients and/or HIV care residents;

(e) The facility must develop and implement plans for improvement to address deficiencies identified by the performance improvement program and must document the outcome of the remedial action;

(f) Performance improvement program records are not disclosable except when such disclosure is required to demonstrate compliance with this section;

(g) Good faith attempts by the Performance Improvement Program Committee to identify and correct deficiencies will not be used as a basis for sanctions.

(7) Infection Control.

(a) The residential hospice must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

(Rule 1200-8-15-.06, continued)

(b) The administrator shall assure that an infection control committee, including the medical director and members of the nursing staff and administrative staff, develops guidelines and techniques for the prevention, surveillance, control and reporting of facility infections. Duties of the committee shall include the establishment of:

1. Written infection control policies;

2. Techniques and systems for identifying, reporting, investigating and controlling infections in the facility;

3. Written procedures governing the use of aseptic techniques and procedures in the facility;

4. Written procedures concerning food handling, laundry practices, disposal of environmental and patient and/or resident wastes, traffic control and visiting rules, sources of air pollution, and routine culturing of autoclaves and sterilizers;

5. A log of incidents related to infectious and communicable diseases;

6. Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as handwashing, proper grooming, masking and dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient and/or resident equipment and supplies; and,

7. Continuing education for all facility personnel on the cause, effect, transmission, prevention, and elimination of infections.

(c) The administrator, the medical director and a registered nurse must ensure that the facility-wide performance improvement program and training programs address problems identified by the infection control program and must be responsible for the implementation of successful corrective action plans in affected problem areas.

(d) The facility shall develop policies and procedures for testing a patient's or resident's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the facility, a student studying at the facility, or other health care provider rendering services at the facility is exposed to a patient's or resident's blood or other body fluid. The testing shall be performed at no charge to the patient or resident, and the test results shall be confidential.

(e) The facility and its employees shall adopt and utilize standard or universal precautions for preventing transmission of infections, HIV, and communicable diseases.

(f) Every residential hospice shall adopt appropriate policies regarding the testing of patients and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome.

(g) Precautions shall be taken to prevent the contamination of sterile supplies by soiled supplies. Sterile supplies shall be packaged and stored in a manner that protects the sterility of the contents. Decontamination and preparation areas shall be separated.

(h) Space and facilities for housekeeping equipment and supply storage shall be provided in each service area. Storage for bulk supplies and equipment shall be located away from patient and resident care areas. The building shall be kept in good repair, clean, sanitary and safe at all times.

(i) The facility shall appoint a housekeeping supervisor who shall be responsible for:

(Rule 1200-8-15-.06, continued)

1. Organizing and coordinating the facility's housekeeping service;

2. Acquiring and storing sufficient housekeeping supplies and equipment for facility maintenance; and,

3. Assuring the clean and sanitary condition of the facility to provide a safe hygienic environment for patients and/or residents and staff. Cleaning shall be accomplished in accordance with the infection control rules and regulations herein and facility policy.

(j) Laundry facilities located in the residential hospice shall:

1. Be equipped with an area for receiving, processing, storing and distributing clean linen;

2. Be located in an area that does not require transportation for storage of soiled or contaminated linen through food preparation, storage or dining areas;

3. Provide space for storage of clean linen and for bulk storage within clean areas of the facility; and,

4. Provide carts, bags or other acceptable containers appropriately marked to identify those used for soiled linen and those used for clean linen to prevent dual utilization of the equipment and cross contamination.

(k) The facility shall name an individual who is responsible for laundry service. This individual shall be responsible for:

1. Establishing a laundry service, either within the residential hospice or by contract, that provides the facility with sufficient clean, sanitary linen at all times;

2. Knowing and enforcing infection control rules and regulations for the laundry service;

3. Assuring the collection, packaging, transportation and storage of soiled, contaminated, and clean linen is in accordance with all applicable infection control rules, regulations and procedures; and,

4. Assuring that a contract laundry service complies with all applicable infection control rules, regulations and procedures.

(8) Hospice Aide Services. Aide Services must be available and adequate in frequency to meet the needs of the patients.

(a) The hospice aide shall be assigned to a particular patient or resident by a registered nurse. Written instructions for patient or resident care shall be prepared by a registered nurse or therapist as appropriate. Duties may include the performance of simple procedures as an extension of therapy services, personal care, ambulation and exercises, reporting changes in the patient's or resident's condition and needs, and completing appropriate records.

(b) The registered nurse, or appropriate professional staff member, shall monitor and assess the hospice aide's competence in providing care, relationships and determine whether goals are being met.

(c) There shall be regularly scheduled continuing in-service programs which include on-the-job training as issues are identified.

(Rule 1200-8-15-.06, continued)

(9) Physical therapy, occupational therapy, respiratory therapy and speech language pathology. Physical therapy services, occupational therapy services, respiratory therapy services and speech language pathology services must be available, and when provided, offered in a manner consistent with accepted standards of practice.

(10) Medical supplies. Medical supplies and appliances including drugs and biologicals, must be provided as needed for the palliation and management of the terminal illness or conditions directly attributable to the terminal diagnosis.

(a) Administration. All drugs and biologicals must be administered in accordance with accepted standards of practice, only by appropriately licensed employees of the hospice.

(b) The residential hospice must have a policy for the disposal of controlled drugs when those drugs are no longer needed by the patient.

(c) Drugs and biologicals may be administered by the patient or resident or his/her family member if the patient's or resident's attending physician has approved.

(11) Medical Records.

(a) A medical record containing past and current findings in accordance with accepted professional standards shall be maintained for every residential hospice patient and/or HIV care resident. The record must be complete, promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval. Each clinical record is a comprehensive compilation of information. Entries are made for all services provided. Entries are made and signed by the person providing the services. The record includes all services whether furnished directly or under arrangements made by the hospice. Each individual's record must contain:

1. The initial and subsequent assessments;

2. The plan of care;

3. Identification data;

4. Consent and authorization and election forms;

5. Pertinent medical history; and

6. Complete documentation of all services and events, including but not limited to evaluations, treatments and progress notes.

(b) All medical records, either written, electronic, graphic or otherwise acceptable form, must be retained in their original or legally reproduced form for a minimum period of at least (10) years after which such records may be destroyed. However, in cases of patients or residents under mental disability or minority, their complete residential hospice records shall be retained for the period of minority or known mental disability, plus one (1) year, or ten (10) years following the discharge of the patient or resident, whichever is longer. Records destruction shall be accomplished by burning, shredding or other effective method in keeping with the confidential nature of the contents. The destruction of records must be made in the ordinary course of business, must be documented and in accordance with the residential hospice's policies and procedures, and no record may be destroyed on an individual basis.

(c) Even if the residential hospice discontinues operations, records shall be maintained as mandated by these rules and the Tennessee Medical Records Act (see T.C.A. §§ 68-11-308). If a patient or resident is transferred to another health care facility or agency, a copy of the record or an

abstract shall accompany the patient or resident when the residential hospice is directly involved in the transfer.

(d) The residential hospice must have a procedure for ensuring the confidentiality of patient and resident records. Information from, or copies of, records may be released only to authorized individuals, and the facility must ensure that unauthorized individuals cannot gain access to, or alter, patient or resident records. Original medical records must be released by the facility only in accordance with federal and state laws.

(e) For purposes of this rule, the requirements for signature or countersignature by a physician or other person responsible for signing, countersigning and entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established protocol or rules.

(f) All entries must be legible, complete, dated and authenticated according to facility policy.

(12) Pharmaceutical Services.

(a) The residential hospice shall have pharmaceutical services that meet the needs of the residents and are in accordance with the Tennessee Board of Pharmacy statutes and regulations. The facility is responsible for developing policies and procedures that minimize drug errors.

(b) Test reagents, germicides, and disinfectants shall be stored separately from drugs, devices and related materials. External drugs and related materials must be stored separately from internal drugs, devices and related materials. All drugs, devices and related materials must be properly labeled. They shall be properly stored in medicine compartments, including cabinets on wheels, or drug rooms. Such cabinets or drug rooms shall be kept securely locked when not in use and the key must be in the possession of the supervising nurse or other authorized persons.

(c) Schedule II drugs must be stored behind two (2) separately locked doors at all times and accessible only to persons in charge of administering medication.

(d) Every residential hospice shall comply with all state and federal regulations governing Schedule II drugs.

(e) A notation shall be made in a Schedule II drug book and in the patient's or resident's nursing notes each time a Schedule II drug is given. The notation shall include the name of the patient or resident receiving the drug, name of the drug, the dosage given, the method of administration, the date and time given and the name of the physician prescribing the drug.

(f) All oral orders shall be immediately recorded, designated as such and signed by the person receiving them and countersigned by the physician within ten (10) days.

(g) All orders for drugs, devices and related materials must be in writing and signed by the practitioner or practitioners responsible for the care of the patient or resident. Electronic and computer-generated records and signature entries are acceptable. When telephone or oral orders must be used, they shall be:

1. Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with federal and state law; and,

2. Signed or initialed by the prescribing practitioner according to residential hospice policy.

(Rule 1200-8-15-.06, continued)

(h) Medications not specifically limited as to time or number of doses when ordered are controlled by automatic stop orders or other methods in accordance with written policies. No Schedule II drug shall be given or continued beyond seventy-two (72) hours without a written order by the physician.

(i) Medication administration records (MAR) shall be checked against the physician's orders. Each dose shall be properly recorded in the clinical record after it has been administered.

(j) Preparation of doses for more than one scheduled administration time shall not be permitted.

(k) Medication shall be administered only by licensed medical or licensed nursing personnel or other licensed health professionals acting within the scope of their license.

(l) Unless the unit dose package system is used, individual prescriptions of drugs shall be kept in the original container with the original label intact showing the name of the patient or resident, the drug, the physician, the prescription number and the date dispensed.

(m) Legend drugs shall be dispensed by a licensed pharmacist.

(n) Any unused portions of prescriptions shall be turned over to the patient or resident only on a written order by the physician. A notation of drugs released to the patient or resident shall be entered into the medical record. All unused prescriptions left in a residential hospice must by destroyed on the premises and recorded by a pharmacist. Such record shall be kept in the residential hospice.

(13) Laboratory Services.

The residential hospice must maintain or have available, either directly or through a contractual agreement, adequate laboratory services to meet the needs of the patients and/or residents. The residential hospice must ensure that all laboratory services provided to its patients and/or residents are performed in a facility licensed in accordance with the Tennessee Medical Laboratory Act (TMLA). All technical laboratory staff shall be licensed in accordance with the TMLA and shall be qualified by education, training and experience for the type of services rendered.

(14) Food and Dietetic Services.

(a) The residential hospice must designate a person, either directly or by contractual agreement, to serve as the food and dietetic services director with responsibility for the daily management of the dietary services.

(b) There must be a qualified dietitian, full time, part-time, or on a consultant basis who is responsible for the development and implementation of a nutrition care process to meet the needs of patients and/or residents for health maintenance, disease prevention and, when necessary, medical nutrition therapy to treat an illness, injury or condition.

(c) Menus must meet the needs of the patients and/or residents.

1. Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients and/or residents and must be prepared and served as prescribed.

2. Special diets shall be prepared and served as ordered.

3. Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients and/or residents.

4. A current therapeutic diet manual approved by the dietitian and medical director must be readily available to all medical, nursing, and food service personnel.

(d) Education programs, including orientation, on-the-job training, inservice education, and continuing education shall be offered to dietetic services personnel on a regular basis. Programs shall include instruction in the use of equipment, personal hygiene, proper inspection, and the handling, preparing and serving of food.

(e) A minimum of three (3) meals in each twenty-four (24) hour period shall be offered. A supplemental night meal shall be offered if more than fourteen (14) hours lapse between supper and breakfast. Additional nourishments shall be provided to patients and/ or residents with special dietary needs. A minimum of three (3) days supply of food shall be on hand.

(f) Food shall be protected from dust, flies, rodents, unnecessary handling, droplet infection, overhead leakage and other sources of contamination whether in storage, while being prepared and served, and/or transported through hallways.

(g) Perishable food shall not be allowed to stand at room temperature except during necessary periods of preparation or serving. Prepared foods shall be kept hot (140°F or above) or cold (45°F or less). Appropriate equipment for temperature maintenance, such as hot and cold serving units or insulated containers, shall be used.

(h) Dishwashing machines shall be used according to manufacturer specifications.

(i) All dishes, glassware and utensils used in the preparation and serving of food and drink shall be cleaned and sanitized after each use.

(j) The cleaning and sanitizing of handwashed dishes shall be accomplished by using a three-compartment sink according to the current "U.S. Public Health Service Sanitation Manual".

(k) The kitchen shall contain sufficient refrigeration equipment and space for the storage of perishable foods.

(l) All refrigerators and freezers shall have thermometers. Refrigerators shall be kept at a temperature not to exceed 45°F. Freezers shall be kept at a temperature not to exceed 0°F.

(m) Written policies and procedures shall be followed concerning the scope of food services in accordance with the current edition of the "U.S. Public Health Service Recommended Ordinance and Code Regulating Eating and Drinking Establishments" and the current "U.S. Public Health Service Sanitation Manual" should be used as a guide to food sanitation.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000.*

1200-8-15-.07 RESERVED.

1200-8-15-.08 BUILDING STANDARDS.

(1) The residential hospice must be constructed and arranged to ensure the safety of the patient and/or resident.

(2) After the application and licensure fees have been submitted, the building construction plans must be submitted to the department. All new facilities shall conform to the 1999 edition of the Standard

Building Code (excluding Chapter I, Administration and Chapter 11, Handicapped Accessibility), the handicap code as required by T.C.A. §68-18-204(a), the most recent edition of the ASHRAE Handbook of Fundamentals, the 2000 edition of the National Fire Protection Code (NFPA), NFPA 1 including Annex A, the 1999 National Electrical Code and the 2001 Edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities. When referring to height, area or construction type, the Standard Building Code shall prevail. All new and existing facilities are subject to the requirements of the Americans with Disabilities Act (A.D.A.). Where there are conflicts between requirements in the above listed codes and regulations and provisions of this chapter, the most restrictive shall apply.

(3) All new construction and renovations to existing facilities, other than alterations not affecting fire and life safety or functional issues, shall be performed in accordance with the specific requirements of these regulations governing new construction in residential hospices, including the submission of phased construction plans and the final work drawings and the specifications to each.

(4) No new residential hospice shall hereafter be constructed, nor shall major alterations be made to existing residential hospices, without the prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new residential hospice is licensed or before any alteration or expansion of a residential hospice can be approved, the applicant must furnish two (2) complete sets of plans and specifications to the department, together with fees and other information as required. Plans and specifications for new construction and major renovations, other than minor alterations not affecting fire and life safety or functional issues shall be prepared by or under the direction of a licensed architect and/or a qualified licensed engineer.

(5) In the event that submitted materials do not appear to satisfactorily comply with 1200-8-15-.08(2), the department shall furnish a letter to the party submitting the plans which shall list the particular items in question and request further explanation and/or confirmation of necessary modifications.

(6) The codes in effect at the time of submittal of plans and specifications shall be the codes to be used throughout the project.

(7) Detailed plans shall be drawn to a scale of at least one-eighth inch equals one foot (1/8" = 1'), and shall show the general arrangement of the building, the intended purpose and the fixed equipment in each room, with such additional information as the department may require. These plans shall be prepared by an architect or engineer licensed to practice in the State of Tennessee. The plans shall contain a certificate signed by the architect or engineer that to the best of his or her knowledge or belief the plans conform to all applicable codes.

(a) A plan shall be forwarded to the appropriate section of the department for review. After receipt of approval of the plans, the owner may proceed with site grading and foundation work prior to receipt of approval of final plans and specifications with the understanding that such work is at the owner's risk and without assurance that final approval of final plans and specifications shall be granted. Final plans and specifications shall be submitted for review and approval. Final approval must be received before proceeding beyond foundation work.

(b) Review of plans does not eliminate responsibility of owner and/or architect to comply with all rules and regulations.

(8) Specifications shall supplement all drawings. They shall describe the characteristics of all materials, products and devices, unless fully described and indicated on the drawings. Specification copies shall be bound in an 8½ x 11 inch folder.

(Rule 1200-8-15-.08, continued)

(9) Final review of plans and specifications shall be acknowledged in writing with copies sent to the architect and the owner, manager or other executive of the institution. The distribution of such review may be modified at the discretion of the department.

(10) All construction shall be executed in accordance with the completed plans and specifications.

(11) Drawings and specifications shall be prepared for each of the following branches of work: architectural, structural, mechanical and electrical.

(12) Architectural drawings shall include:

(a) Plot plan(s) showing property lines, finish grade, location of existing and proposed structures, roadways, walks, utilities and parking areas;

(b) Floor plan(s) showing scale drawings of typical and special rooms, indicating all fixed and movable equipment and major items of furniture;

(c) Separate life safety plans showing the compartment(s), all means of egress and exit markings, exits and travel distances, dimensions of compartments and calculation and tabulation of exit units. All fire and smoke walls must be color-coded;

(d) The elevation of each facade;

(e) The typical sections throughout the building;

(f) The schedule of finishes;

(g) The schedule of doors and windows;

(h) Roof plans;

(i) Details and dimensions of elevator shaft(s), car platform(s), doors, pit(s), equipment in the machine room, and the rates of car travel must be indicated for elevators; and,

(j) Code analysis.

(13) Structural drawings shall include:

(a) Plans of foundations, floors, roofs and intermediate levels which show a complete design with sizes, sections and the relative location of the various members; and,

(b) Schedules of beams, girders and columns.

(14) Mechanical drawings shall include:

(a) Specifications which show the complete heating, ventilating, fire protection, medical gas systems and air conditioning systems;

(b) Water supply, sewerage and HVAC piping systems;

(c) Pressure relationships which shall be shown on all floor plans;

(d) Heating, ventilating, HVAC piping, medical gas systems and air conditioning systems with all related piping and auxiliaries to provide a satisfactory installation;

(Rule 1200-8-15-.08, continued)

(e) Water supply, sewage and drainage with all lines, risers, catch basins, manholes and cleanouts clearly indicated as to location, size, capacities, and location and dimensions of septic tank and disposal field; and,

(f) Color coding to show clearly supply, return and exhaust systems.

(15) Electrical drawings shall include:

(a) A certification that all electrical work and equipment are in compliance with all applicable local codes and laws, and that all materials are currently listed by recognized testing laboratories;

(b) All electrical wiring, outlets, riser diagrams, switches, special electrical connections, electrical service entrance with service switches, service feeders and characteristics of the light and power current, and transformers when located within the building;

(c) The electrical system, which shall comply with applicable codes, and shall include:

1. The nurses call system;

2. The paging system;

3. The fire alarm system; and,

4. The emergency power system including automatic services as defined by the codes.

(d) Color coding to show all items on emergency power.

(16) Final working drawings and specifications shall be accurately dimensioned and include all necessary explanatory notes, schedules and legends. The working drawings and specifications shall be complete and adequate for contract purposes. One (1) set of final plans shall be submitted to the department, after final approval is given but prior to occupancy, in such a form as approved by the department.

(17) No system of water supply, plumbing, sewage, garbage or refuse disposal shall be installed nor shall any existing system be materially altered or extended until complete plans and specifications for the installation, alteration or extension have been submitted to the department and show that all applicable codes have been met and necessary approval has been obtained.

(a) Before the facility is used, the water supply system shall be approved by the Tennessee Department of Environment and Conservation.

(b) Sewage shall be discharged into a municipal system or approved package system where available; otherwise, the sewage shall be treated and disposed of in a manner of operation approved by the Department of Environment and Conservation and shall comply with existing codes, ordinances and regulations which are enforced by cities, counties or other areas of local political jurisdiction.

(18) Construction and renovation projects shall provide for the safety and protection of patients and/or residents and personnel.

(19) Construction, equipment, and installation of dietary facilities shall comply with the standards specified in the current Public Health Service “Food Service Sanitation Manual.”

(20) The facility must be designed and equipped for the comfort and privacy of each hospice patient and or HIV care resident and family member(s) by providing physical space for private patient/family or resident/family visiting, accommodations for family members to remain with the patient and/or

resident throughout the night, accommodations for family privacy following a patient's or resident's death, and decor which is home-like in design and function.

(21) The physical environment must be maintained in such a manner to assure the safety and well being of the patients and/or residents.

(a) Any condition on the residential hospice site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.

(b) Telephones shall be readily accessible and at least one (1) shall be equipped with sound amplification and shall be accessible to wheelchair patients and/or residents.

(c) Equipment and supplies for physical examination and emergency treatment of patients and/or residents shall be made available.

(d) A bed complete with mattress and pillow shall be provided. In addition, patients and/or residents units shall be provided with at least one chair, a bedside table, an over bed tray and adequate storage space for toilet articles, clothing and personal belongings.

(e) Individual wash cloths, towels and bed linens must be provided for each patient and/or resident. Linen shall not be interchanged from patient to patient or resident to resident until it has been properly laundered.

(f) Bath basin water service, emesis basin, bedpan and urinal shall be individually provided.

(g) Items of equipment coming into intimate contact with patients and/or residents shall be disinfected or sterilized after each use unless individual equipment for each is provided and then sterilized or disinfected between patients and/or residents and as often as necessary to maintain them in a clean and sanitary condition. Single use, disposable items are acceptable but shall not be reused.

(h) The facility shall have written policies and procedures governing care of patients and/or residents during the failure of the air conditioning, heating or ventilation system, including plans for hypothermia and hyperthermia. When the temperature of any patient/resident area falls below 65°F. or exceeds 85°F., or is reasonably expected to, the facility shall be alerted to the potential danger, and the Department shall be notified.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed February 18, 2003; effective May 4, 2003.*

1200-8-15-.09 LIFE SAFETY.

(1) Any residential hospice which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations.

(2) The residential hospice shall provide fire protection by the elimination of fire hazards, by the installation of necessary fire fighting equipment and by the adoption of a written fire control plan.

(Rule 1200-8-15-.09, continued)

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000.*

1200-8-15-.10 INFECTIOUS AND HAZARDOUS WASTE.

(1) Each residential hospice must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous wastes. These policies and procedures must comply with the standards of this section and all other applicable state and federal regulations.

(2) The following waste shall be considered to be infectious waste:

(a) Waste contaminated by patients/residents who are isolated due to communicable disease, as provided in the U.S. Centers for Disease Control "Guidelines for Isolation Precautions in Hospitals";

(b) Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, culture dishes and devices used to transfer, inoculate, and mix cultures;

(c) Waste human blood and blood products such as serum, plasma, and other blood components;

(d) All discarded sharps (including but not limited to, hypodermic needles, syringes, pasteur pipettes, broken glass and scalpel blades) used in patient/resident care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories;

(e) Other waste determined to be infectious by the facility in its written policy.

(3) Infectious and hazardous waste must be segregated from other waste at the point of generation (i.e., the point at which the material becomes a waste) within the facility.

(4) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported, prior to treatment and disposal.

(a) Contaminated sharps must be directly placed in leakproof, rigid, and puncture-resistant containers which must then be tightly sealed;

(b) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of infectious waste must be conspicuously identified. Packages containing infectious waste which pose additional hazards, including but not limited to, chemical and radiological must also be conspicuously identified to clearly indicate those additional hazards;

(c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste; and,

(d) Opaque packaging must be used for pathological waste.

(5) After packaging, waste must be handled and transported by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.

(a) Waste must not be compacted or ground (i.e., in a mechanical grinder) prior to treatment, except that pathological waste may be ground prior to disposal; and,

(b) Plastic bags of infectious waste must be transported by hand.

(6) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons. Waste must be stored in a manner and location which affords protection from animals, precipitation, wind, direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.

(7) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the facility must ensure that proper actions are immediately taken to:

(a) Isolate the area from the public and non-essential personnel;

(b) To the extent practicable, repackage all spilled waste and contaminated debris in accordance with the requirements of this section;

(c) Sanitize all contaminated equipment and surfaces appropriately and in accordance with written policies and procedure; and,

(d) Complete an incident report and maintain a copy on file.

(8) Except as provided otherwise in this section, a facility must treat or dispose of infectious waste by one or more of the methods specified in this part.

(a) A facility may treat infectious waste in an on-site sterilization or disinfection device, or in an incinerator or a steam sterilizer, which has been designed, constructed, operated and maintained so that infectious waste treated in such a device is rendered non-infectious and is, if applicable, authorized for that purpose pursuant to current rules of the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each sterilizing or disinfecting cycle must contain appropriate indicators to assure conditions were met for proper sterilization or disinfection of materials included in the cycle, and records kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Infectious waste that has been rendered to a carbonized or mineralized ash shall be deemed non-infectious, unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation, such ash shall be disposable as a (non-hazardous) solid waste under current rules of the Department of Environment and Conservation.

(b) The facility may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. § 69-3-101, et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.

(c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county, and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.

(9) The facility may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is in Tennessee,

the facility must ensure that it has all necessary state and local approvals, and such approvals shall be available for review. If the off-site location is in another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable federal and state requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.

(10) All garbage, trash and other non-infectious waste shall be stored and disposed of in a manner that shall not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, constructed of easily-cleanable material and shall be kept on elevated platforms.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000.*

1200-8-15-.11 RECORDS AND REPORTS.

(1) A yearly statistical report, the "Joint Annual Report" shall be submitted to the department. The forms are mailed to each residential hospice by the department each year. The forms must be completed and returned to the department as requested.

(2) The residential hospice shall report each case of communicable disease to the local county health officer in the manner provided by existing regulations. Failure to report a communicable disease may result in disciplinary action, including revocation of the facility's license.

(3) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.

(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:

1. medication errors;

2. aspiration in a non-intubated patient related to conscious/moderate sedation;

3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;

4. volume overload leading to pulmonary edema;

5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;

6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;

7. burns of a second or third degree;

(Rule 1200-8-15-.11, continued)

8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;

9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

(i) procedure related injury requiring repair or removal of an organ;

(ii) hemorrhage;

(iii) displacement, migration or breakage of an implant, device, graft or drain;

(iv) post operative wound infection following clean or clean/contaminated case;

(v) any unexpected operation or reoperation related to the primary procedure;

(vi) hysterectomy in a pregnant woman;

(vii) ruptured uterus;

(viii) circumcision;

(ix) incorrect procedure or incorrect treatment that is invasive;

(x) wrong patient/wrong site surgical procedure;

(xi) unintentionally retained foreign body;

(xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;

(xiii) criminal acts;

(xiv) suicide or attempted suicide;

(xv) elopement from the facility;

(xvi) infant abduction, or infant discharged to the wrong family;

(xvii) adult abduction;

(xviii) rape;

(xix) patient altercation;

(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;

(xxi) restraint related incidents; or

(xxii) poisoning occurring within the facility.

(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:

1. strike by the staff at the facility;

2. external disaster impacting the facility;

3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and

4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.

(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.

(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.

(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.

(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in

(Rule 1200-8-15-.11, continued)

(a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.

(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.

(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.

(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.

(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.

(4) The residential hospice shall retain legible copies of the following records and reports for thirty-six (36) months following their issuance. They shall be maintained in a single file, and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(d) Department licensure and fire safety inspections and surveys;

(e) Federal Health Care Financing Administration surveys and inspections, if any;

(f) Orders of the Commissioner or Board, if any;

(g) Comptroller of the Treasury's audit reports and finding, if any; and,

(h) Maintenance records of all safety equipment.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, and 68-11-216.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-8-15-.12 PATIENT/RESIDENT RIGHTS.

(1) The residential hospice shall establish and implement written policies and procedures setting forth the rights of patients and residents for the protection and preservation of dignity and individuality. Each patient and resident has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To privacy, for visits by his/her spouse or significant other;

(c) To share a room with his/her spouse or significant other;

(d) To be different in order to promote social, religious, and psychological well being;

(e) To privately talk and/or meet with and see any person;

(f) To send and receive mail promptly and unopened;

(g) To be free from mental and physical abuse. Should this right be violated, the facility must notify the Department within five (5) business days of the incident and the Tennessee Department of Human Services, Adult Protective Services as required by T.C.A. §71-6-101 et seq;

(h) To be free from chemical and physical restraints;

(i) To meet and take part in activities of social, commercial, religious, and community groups. The administrator may refuse access to the facility to any person if that person's presence would be injurious to the health and safety of a patient/resident or staff, or would threaten the security of the property of the patient or resident, staff or facility;

(j) To retain and use personal clothing and possessions as space permits;

(k) To be free from being required by the facility to work or perform services;

(l) To be fully informed by a physician of his/her health and medical condition. The facility shall give the patient or resident and family the opportunity to participate in planning the patient's or resident's care and medical treatment;

(m) To have appropriate assessment and management of pain;

(n) To be involved in the decision making of all aspects of their care;

(o) To refuse treatment. The patient or resident must be informed of the consequences of that decision. The refusal and its reason must be reported to the physician and documented in the medical record;

(p) To refuse experimental treatment and drugs. The patient's or resident's written consent for participation in research must be obtained and retained in the medical record;

(q) To have records kept confidential and private. Written consent by the patient or resident must be obtained prior to release of information except to persons authorized by law. If the patient or resident is mentally incompetent, written consent is required from the patient's or resident's legal representative. The residential hospice must have policies to govern access and duplication of the patient's or resident's record;

(Rule 1200-8-15-.12, continued)

(r) To manage personal financial affairs. Any request by the patient or resident for assistance must be in writing. A request for any additional person to have access to a patient's or resident's funds must also be in writing;

(s) To be told in writing before or at the time of admission about the services available in the facility, about any extra charges and charges for services not covered;

(t) To be free from discrimination because of the exercise of the right to speak and voice complaints;

(u) To exercise his/her own independent judgment by executing any documents, including admission forms; and

(v) To voice grievances and complaints, and to recommend changes in policies and services to the facility staff, or outside representatives of the patient's or resident's choice. The facility shall establish a grievance procedure and fully inform the patient or resident and family of same.

(2) The rights set forth in this section may be abridged, restricted, limited or amended only as follows:

(a) When medically contraindicated;

(b) When necessary to protect and preserve the rights of the patients or residents in the facility; or

(c) When contradicted by the explicit provisions of another rule of the board.

(3) Any reduction in patients' or resident's rights must be explicit, reasonable, appropriate to the justification, the least restrictive response feasible, shall be explained to the patient or resident, and must be documented in the individual patient's or resident's record by reciting the limitation's reason and scope.

(4) Patients' and/or residents' pets and other animals utilized for pet therapy programs shall be allowed in the facility. The facility shall designate in its policies and procedures those areas where animals will be excluded. The areas designated shall be determined based upon an assessment of the facility performed by medically trained personnel.

(5) Each patient or resident has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment (including resuscitative services). This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed June 18, 2002; effective September 1, 2002.*

1200-8-15-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING FOR INCOMPETENT PATIENTS OR RESIDENTS.

(1) Pursuant to this Rule, each residential hospice shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient or resident who is incompetent or who lacks decision-making capacity, including but not limited to allowing the withholding of CPR measures from individual patients or residents. The policies and procedures for determining when resuscitative services may be withheld must respect the patient's or resident's rights of self-determination. The residential hospice must inform the patient or resident and/or the patient's or resident's health care decision-maker of these policies and procedures upon admission or at such time as may be appropriate.

(Rule 1200-8-15-.13, continued)

(2) The residential hospice should identify, after consultation with the family or responsible party, the name of the health care decision-maker for a patient or resident who is incompetent or who lacks decision-making capacity, who will be responsible, along with the treating physician, for making health care decisions, including but not limited to deciding on the issuance of a DNR order.

(3) Health care decisions made by a health care decision-maker must be made in accord with the patient's or resident's individual health care instructions, if any, and other wishes to the extent known to the health care decision-maker. If the patient's or resident's specific wishes are not known, decisions are to be made in accord with the health care decision-maker's determination of the patient's or resident's desires or best interests in light of the personal values and beliefs of the patient or resident to the extent they are known.

(4) In the case of a patient or resident who lacks decision-making capacity and who has not appointed an individual to act on his or her behalf pursuant to an advance directive and who does not have a court-appointed guardian or conservator with health care decision-making authority, documentation in the medical record must identify the patient's or resident's surrogate to make health care decisions on the patient's or resident's behalf.

(a) The patient's or resident's surrogate shall be an adult who:

1. has exhibited special care and concern for the patient or resident, who is familiar with the patient's or resident's personal values, and who is reasonably available; and

2. consideration shall if possible be given in order of descending preference for service as a surrogate to:

(i) the patient's or resident's spouse,

(ii) the patient's or resident's adult child,

(iii) the patient's or resident's parent,

(iv) the patient's or resident's adult sibling,

(v) any other adult relative of the patient or resident, or

(vi) any other adult who satisfies the requirement under part 1 above.

(b) If none of the individuals eligible to act as a surrogate under subparagraph (a), is reasonably available, the patient's or resident's treating physician may make health care decisions for the patient or resident after the treating physician either (i) consults with and obtains the recommendations of an institutional ethics committee, or (ii) consults with a second physician who (A) is not directly involved in the patient's or resident's health care; (B) either (i) does not serve in a capacity of decision-making or influence or responsibility over the treating physician, or (ii) for whom the treating physician does not exert decision-making, influence or responsibility; and (C) concurs with the treating physician's decision. For the purposes of this rule, "institutional ethics committee" means a committee of a licensed health care institution which renders advice concerning ethical issues involving health care.

(5) All patients or residents shall be presumed as having consented to CPR unless there is documentation in the medical record that the patient or resident has specified that a DNR order be written. DNR orders may be written to exclude any portion of the CPR measures deemed to be unacceptable.

(6) In the case of an incompetent patient or resident who has appointed an attorney in fact to act on his or her behalf pursuant to an advance directive or who has a court-appointed guardian or conservator with

(Rule 1200-8-15-.13, continued)

health care decision-making authority, documentation in the medical record must reflect that the attorney in fact, guardian or conservator has specified that a DNR order be written. In the case of a patient or resident who lacks decision-making capacity and who has not appointed an individual to act on his or her behalf pursuant to an advance directive and who does not have a court-appointed guardian or conservator with health care decision-making authority, documentation in the medical record must identify the patient's or resident's surrogate to make health care decisions on the patient's or resident's behalf, and reflect that the patient's or resident's surrogate and the patient's or resident's treating physician have mutually specified that a DNR order be written.

(7) CPR may be withheld from the patient or resident if in the judgment of the treating physician an attempt to resuscitate would be medically futile. Withholding and withdrawal of resuscitative services shall be regarded as identical for the purposes of these regulations.

(8) Procedures for periodic review of DNR orders must be established and maintained. The residential hospice must have procedures for allowing revocation or amending DNR orders by the patient or resident, the patient's or resident's health care decision-maker, or treating physician. Such change shall be documented in the medical record.

(9) Any treating physician who refuses to enter a DNR order in accordance with provisions set forth above, or to comply with a DNR order, shall promptly advise the patient or resident or the patient's or resident's health care decision-maker of this decision. The treating physician shall then:

(a) Make a good faith attempt to transfer the patient or resident to another physician who will honor the DNR order; and,

(b) Permit the patient or resident to obtain another physician.

(10) Each residential hospice shall establish, and set forth in writing, a mediation process to deal with any dispute regarding health care decisions, including DNR orders, or the determination of the health care decision-maker.

(11) This rule does not alter any requirements imposed by state or federal law, where applicable, including Title 33, the mental health and developmental disabilities law.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-224.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed April 28, 2003; effective July 12, 2003.*

1200-8-15-.14 DISASTER PREPAREDNESS.

(1) Emergency Electrical Power.

(a) All residential hospices must have one or more on-site electrical generators, which are capable of providing emergency electrical power to at least all life sustaining equipment and life sustaining resources such as: ventilators; blood banks, biological refrigerators, safety switches for boilers, safety lighting for corridors and stairwells and other essential equipment.

(b) Connections shall be through a switch which shall automatically transfer the circuits to the emergency power source in case of power failure. It is recognized that some equipment may not sustain automatic transfer and provisions will have to be made to manually change these items from a non-emergency powered outlet to an emergency powered outlet or other power source. All emergency power transfer switches shall be labeled as such. Switches affecting heat, ventilation, and all systems shall be labeled.

(Rule 1200-8-15-.14, continued)

(c) The emergency power system shall have a minimum of twenty four (24) hours of either propane, gasoline or diesel fuel. The quantity shall be based on its expected or known connected load consumption during power interruptions. In addition, the residential hospice shall have a written contract with an area fuel distributor which guarantees first priority service for re-fills during power interruptions.

(d) The emergency power system (generator) shall be inspected weekly and exercised and under actual load and operating temperature conditions for at least thirty (30) minutes, once each month including automatic and manual transfer of equipment. The generator shall be exercised by trained facility staff who are familiar with the systems operation. Instructions for the operation of the systems and the manual transfer of emergency power shall be maintained with the facility's disaster preparedness plan and shall be separately identified in the plan. Records shall be maintained for all weekly inspections and monthly tests and be kept on file for a minimum of three (3) years.

(2) Physical Facility and Community Emergency Plans.

(a) Physical Facility (Internal Situations).

1. Every residential hospice shall have a current internal emergency plan, or plans, that provides for fires, bomb threats, severe weather, utility service failures, plus any local high risk situations such as floods, earthquakes, toxic fumes and chemical spills. The plan should consider the probability of the types of disasters which might occur, both natural and "man-made".

2. The plan(s) must include provisions for the relocation of persons within the building and/or either partial or full building evacuation. Plans that provide for the relocation of patients and/or residents to other health care facilities must have written agreements for emergency transfers. The agreements may be mutual, i.e. providing for transfers either way.

3. Copies of the plan(s), either complete or outlines, including specific emergency telephone numbers related to that type of disaster, shall be available to all staff. A copy shall be readily available at all times in the telephone operator's position or at the security center. Provisions that have security implications may be omitted from the outline versions.

4. The plan must provide for additional staffing, medical supplies, blood and other resources which would probably be needed.

5. Each of the following disaster preparedness plan drills shall be conducted annually. Drills are for the purpose of educating staff, resource determination, testing personnel safety provisions and communications with other facilities and community agencies. Records of staff orientation, education programs and drills must be maintained for at least three (3) years.

(i) Fire Safety Procedures Plan shall include:

(I) Minor fires

(II) Major fires

(III) Fighting the fire

(IV) Evacuation procedures

(Rule 1200-8-15-.14, continued)

(V) Staff functions by department and job assignment

(VI) Fire drill schedules (fire drills shall be held at least quarterly on each work shift)

(ii) External disaster procedures plan (for tornado, flood, earthquakes) shall include:

(I) Staff duties by department and job assignment

(II) Evacuation procedures

(iii) Bomb Threat Procedures Plan:

(I) Staff duties by department and job assignment

(II) Search team, searching the premises

6. The residential hospice shall develop and periodically review with all employees a pre-arranged plan for the orderly evacuation of all patients and/or residents in case of a fire, internal disaster or other emergency. The plan of evacuation shall be posted throughout the facility. Fire drills shall be held at least quarterly for each work shift for residential hospice personnel in each separate patient/resident-occupied residential hospice building. There shall be a written report documenting the evaluation of each drill and the action recommended or taken for any deficiencies found. Records which document and evaluate these drills must be maintained for at least three (3) years.

7. All fires which result in a response by the local fire department shall be reported to the department within five (5) business days. The report shall contain sufficient information to ascertain the nature and location of the fire, its probable cause and any injuries incurred by any person or persons as a result of the fire. Initial reports by the residential hospice may omit the name(s) of patient(s) and/or resident(s) and other parties involved; however, should the department find the identities of such persons to be necessary to an investigation, the residential hospice shall provide such information.

(b) Emergency Planning with Local Government Authorities.

1. All residential hospices shall establish and maintain communications with the county Emergency Management Agency. This includes the provision of the information and procedures that are needed for the local comprehensive emergency plan. The facility shall cooperate, to the extent possible, in area disaster drills and local emergency situations.

2. Each residential hospice must rehearse both the Physical Facility and Community Emergency plan as required in these regulations, even if the local Emergency Management Agency is unable to participate.

3. A file of documents demonstrating communications and cooperation with the local agency must be maintained.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Amendment filed February 9, 1998; effective April 25, 1998. Repeal and new rule filed April 27, 2000; effective July 11, 2000.*